

## STANDARD MERIT REVIEW LETTER OF INTENT (LOI) FORMAT ALL OFFICE OF RESEARCH AND DEVELOPMENT (ORD) SERVICES (EFFECTIVE 1/1/04)

### **Background:**

Beginning in Spring 2004, ORD is requiring **all Research Service Principal Investigators to submit a LOI prior to submitting a full Merit Review application.** Biomedical Laboratory and Clinical Science R&D Services LOIs should be submitted for Spring 2004 by email (through the local Research Office) to a centrally established VACO email account (email address to be established by 1/1/04). In the future, HSR&D and RR&D will explore electronic LOI submission.

### **Purpose of the Standard LOI:**

- To allow VACO and R&D field staff to plan for Merit Review submissions and subcommittee assignments.
- To ensure that Merit Review applications will be directed to the correct Research Service.
- To establish a common format to present study parameters.
- **NOTE** - PIs who submitted LOIs in August or November 2003 to the Epidemiological, Clinical Research, MREP, or Deployment Health Programs, should not resubmit LOIs.

### **Guideline Definitions:**

**Clinical Science Research and Development (CSR&D)** – any research that focuses on an intact human being as the unit of examination.

For example: This includes interventional and effectiveness studies, clinical epidemiological and technological studies on an intact human being (e.g., neuroimaging).

**Biomedical Laboratory Research and Development (BLR&D)** – any research that explores basic biological/physiological principles in human specimens or animals, not involving an intact human being as the unit of examination.

For example: This includes work focused on animal models or biomedical investigation on tissues, blood or other biologic specimens derived from humans.

### **Spring 2004:**

- **BLR&D and CSR&D** For Spring 2004 only, LOIs will **NOT** be reviewed, only routed to the correct Service portfolio area. After submission of LOIs, PIs may prepare a full application. The cutoff date for LOIs for the Spring 2004 round is **Jan 31, 2004** (*full applications due March 15, 2004*).
- **HSR&D and RR&D** The cutoff date for LOIs for the Spring 2004 round is **March 31, 2004** (*full applications due June 15, 2004*).

## **Instructions for LOI (2 Page Limitation):**

### **1. Each LOI must contain the following materials:**

#### **a. VHA LOI Cover (VA form 10-1313-13)**

(available at <http://www.va.gov/resdev/fr/forms.cfm>)

Check box designating the appropriate Research Service.

#### **b. LOI – Succinctly address each of the following:**

(1) Hypothesis(es)/Research Questions

(2) Discrete Study Objectives

(3) Description of Relevance to VA

(4) Overview of Design/Methods

(5) Description of Intervention(s)/Treatment(s) - *if applicable*

(6) Total Budget and Study Duration

(7) **Statement of Disclosure** – 1-2 sentence statement from the PI indicating that no financial or contractual relationship exists between any organization involved in the proposed study that could constitute a real or apparent conflict of interest (including all investigators and collaborators who plan to devote 5 percent or more effort to the proposed project). If such a relationship or contract does exist, full disclosure must be provided.

#### **c. Acknowledgement of the VA policy to include women and minorities in clinical research (if applicable).**

#### **d. Up to five reference citations.**

### **2. VA ORD Contact for Service-Specific questions:**

<u>Service</u>	<u>Contact (mail code)</u>	<u>Phone</u>	<u>E-mail</u>
CSR&D	Leroy Frey (121)	202-254-0293	leroy.frey@hq.med.va.gov
BLR&D	Leroy Frey (121)	202-254-0293	leroy.frey@hq.med.va.gov
HSR&D	Caryn Cohen (124)	202-254-0218	caryn.cohen@hq.med.va.gov
RR&D	Danielle Kerkovich (122)	202-254-0258	danielle.kerkovich@hq.med.va.gov